

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CITY OF TAYLOR GENERAL	:	Civil Action No. 1:07-cv-10279-GBD
EMPLOYEES RETIREMENT SYSTEM, On	:	
Behalf of Itself and All Others Similarly	:	<u>CLASS ACTION</u>
Situated,	:	
	:	
Plaintiff,	:	
	:	
vs.	:	
	:	
SANOFI-AVENTIS, et al.,	:	
	:	
Defendants.	:	
	:	
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CARRIE SMITH, Individually and On Behalf	:	Civil Action No. 1:08-cv-00021-UA
of All Others Similarly Situated,	:	
	:	<u>CLASS ACTION</u>
	:	
Plaintiff,	:	
	:	
vs.	:	
	:	
SANOFI-AVENTIS, et al.,	:	
	:	
Defendants.	:	
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	X	

MEMORANDUM OF LAW IN SUPPORT OF THE CITY OF EDINBURGH COUNCIL ON
BEHALF OF THE LOTHIAN PENSION FUND AND NEW ENGLAND CARPENTERS
GUARANTEED ANNUITY FUND'S MOTION FOR APPOINTMENT AS LEAD
PLAINTIFF, APPROVAL OF THEIR SELECTION OF LEAD COUNSEL AND
CONSOLIDATION OF RELATED ACTIONS

ORAL ARGUMENT REQUESTED

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. FACTUAL BACKGROUND.....	2
III. ARGUMENT	6
A. The Global Funds Should Be Appointed Lead Plaintiff.....	6
1. The Global Funds Have the Largest Financial Interest in the Relief Sought by the Class.....	7
2. The Global Funds Otherwise Satisfy Rule 23 of the Federal Rules of Civil Procedure	8
B. The Court Should Approve the Global Funds' Selection of Coughlin Stoia as Lead Counsel	9
C. This Court Should Consolidate the Related Actions	10
IV. CONCLUSION.....	11

I. INTRODUCTION

The City of Edinburgh Council on Behalf of the Lothian Pension Fund and New England Carpenters Guaranteed Annuity Fund (“Global Funds”), in connection with their transactions in the publicly-traded securities of Sanofi-Aventis (“Sanofi-Aventis” or the “Company”) between February 17, 2006 and June 13, 2007 (the “Class Period”), submit this memorandum of law in support of their motion pursuant to §21D(a)(3)(B) of the Securities Exchange Act of 1934 (the “Exchange Act”), 15 U.S.C. §78u-4(a)(3)(B), for entry of an order: (1) consolidating related actions; (2) appointing the Global Funds as lead plaintiff for the class; and (3) approving the Global Funds’ selection of Coughlin Stoia Geller Rudman & Robbins LLP (“Coughlin Stoia”) as lead counsel. *See Vanamringe v. Royal Group Techs., Ltd.*, 237 F.R.D. 55, 58 (S.D.N.Y. 2006) (approving Coughlin Stoia as lead counsel).

The Global Funds are the “most adequate plaintiff,” as defined by the Private Securities Litigation Reform Act of 1995 (the “PSLRA”), because, to the best of their knowledge, they have the largest financial interest of any moving class member or plaintiff who has brought suit or filed an application to serve as lead plaintiff.¹ *See generally Rozenboom v. Van Der Moolen Holding, N.V.*, 2004 U.S. Dist. LEXIS 6382 (S.D.N.Y. 2004). In addition, the Global Fund satisfy the requirements of Rule 23 of the Federal Rules of Civil Procedure because their claims are typical of the claims of the putative class and because they will fairly and adequately represent the interests of the class. *See Sofran v. LaBranche & Co.*, 220 F.R.D. 398, 401 (S.D.N.Y. 2004).

¹ *See* Affidavit of David A. Rosenfeld in Support of The City of Edinburgh Council on Behalf of the Lothian Pension Fund’s and New England Carpenters Guaranteed Annuity Fund’s Motion for Appointment as Lead Plaintiff, Approval of Their Selection of Lead Counsel and Consolidation of Related Actions (“Rosenfeld Aff.”), Exs. A and B.

II. FACTUAL BACKGROUND

Sanofi-Aventis is the third largest pharmaceutical company in the world. In 2002, Sanofi-Aventis began testing a new drug, rimonabant (Zimulti in the U.S./Acomplia in Europe), which is a CB1 cannabinoid receptor antagonist, designed to fight obesity by reducing appetite. As the first drug of its class, Zimulti was projected to become extremely profitable for Sanofi-Aventis. Not only did Zimulti show promise for treating obesity, but also for treating other conditions associated with type 2 diabetes and heart disease. Sanofi-Aventis set out to conduct a set of four worldwide phase III clinical trials, called RIO (Rimonabant In Obesity) to study the drug in approximately 6,600 obese or overweight patients. The first of the four studies, RIO-Europe, was published in *The Lancet* on April 16, 2005.

The article stated the following concerning safety: “Similar frequencies of serious adverse events were reported in all groups: except for psychiatric disorders.” And further, “[t]he most common adverse events leading to study discontinuation were depressed mood disorders in all treatment groups.” The article concluded: “Treatment with rimonabant was associated with clinically meaningful weight loss and additional improvements in waist circumference, lipid concentrations, and insulin resistance, and had a favorable safety profile.”

Sanofi-Aventis submitted its New Drug Application (“NDA”) for Zimulti in April 2005 and on June 23, 2005, the Company announced that the Food and Drug Administration (“FDA”) had accepted it for filing. In its press release, the Company stated that Zimulti was “thought to represent a new approach for the comprehensive management of cardiovascular risk factors.”

On November 16, 2005, Sanofi-Aventis issued a press release announcing the publication of the second study, RIO-Lipids, in *The New England Journal of Medicine*.² The release stated that patients on rimonabant “experienced a significant improvement in a range of cardiometabolic risk factors that may contribute to type 2 diabetes and heart disease.” The release also noted findings from the study that patients taking rimonabant experienced a reduction in triglyceride levels and increases in HDL-cholesterol (good cholesterol), as well as “reductions in waist circumference and body weight, improved glucose tolerance, and decreased blood pressure.” The release stated that “the most frequent side effects leading to discontinuation in placebo, rimonabant 5 mg and 20 mg groups included depression (0.6% vs. 1.7% and 2.9%).”

On February 14, 2006, Sanofi-Aventis announced the publication of the RIO-North America study in the *Journal of the American Medical Association*, stating in its heading, “Study Shows Rimonabant Maintains Improvements in Multiple Cardiometabolic Risk Factors For Up to Two Years.”³ The article contains a quote from the Principal Investigator of the study stating that

“[r]imonabant 20 mg once daily produced sustained clinically meaningful weight loss and improvements in associated risk factors during two years of treatment. . . . The sustained improvements we see in several risk factors were beyond what was expected from the observed weight loss and suggests that rimonabant represents an exciting breakthrough in our quest to improve the multiple cardiometabolic risk factors contributing to increased risk for diabetes and heart disease in patients who have abdominal obesity.”

Concerning safety, the press release stated: “In the first year, rimonabant 20 mg once daily was generally well-tolerated and adverse events were mostly mild to moderate.” The release listed

² The results of this study were first revealed at the American College of Cardiology meeting in March 2004.

³ The results of this study were first revealed at the American Heart Association’s meeting in November 2004.

“depressed mood disorder” as one of “[t]he most common adverse events leading to discontinuation.” The release stated that in the second year of the study, adverse events and discontinuations decreased, with “no significant differences” between rimonabant and placebo.

In addition to the four RIO studies, Sanofi-Aventis also conducted a program of three clinical trials called STRATUS (Studies with Rimonabant And Tobacco Use) to study Zimulti for smoking cessation and subsequent prevention of weight gain. STRATUS-US was the first of the studies, the results of which were announced along with the RIO-Lipids study at the American College of Cardiology’s annual meeting in March 2004. The study showed that Zimulti was effective for smoking cessation and researchers reported no differences between the drug and placebo groups with regard to depression and anxiety. The results for the remaining two studies, STRATUS-WW and STRATUS-EU, have not been disclosed.

It became evident through these large studies that Zimulti was very promising and had the potential to become a blockbuster drug with multiple indications. Each study published showed that the drug was effective yet had only minor side effects and produced a low occurrence of only mild to moderate adverse events. Before February 17, 2006, it appeared as though Zimulti would have no problem gaining FDA approval.

On February 17, 2006, upon reviewing Sanofi-Aventis’ NDA, the FDA responded by issuing an approvable letter for Zimulti’s obesity indication. Sanofi-Aventis filed its response to the FDA approvable letter on October 26, 2006. This response contained additional information that the FDA requested regarding the completed Zimulti studies. At this time, Sanofi-Aventis had data from at least four large studies, RIO-Europe, RIO-Lipids, RIO-North America and RIO-Diabetes. On October 27, 2006, Sanofi-Aventis issued a press release announcing the publication of the RIO-Diabetes study in *The Lancet*.

On October 31, 2006, during a conference call, defendant Spek, the Executive Vice President of Pharmaceutical Operations, stated: “[W]e will not speculate at all what the FDA now has to do or will do and within which timeline.” On December 5, 2006, Sanofi-Aventis issued a press release concerning the results of the SERENADE (Study Evaluating Rimonabant Efficacy in Drug-NAïve Diabetic Patients) trial, with the headline “New Data Shows Acomplia (Rimonabant) Benefited Patients with Type 2 Diabetes by Improving Blood Sugar Control, Reducing Weight and Acting on Other Cardiometabolic Risk Factors.” Sanofi-Aventis stated that the study

showed that patients with type 2 diabetes not currently treated with anti-diabetic medications experienced significant improvements in blood sugar control and weight as well as other risk factors such as HDL-cholesterol (good cholesterol) and triglycerides when compared to placebo.

The release also stated that “SERENADE is the second study demonstrating that rimonabant significantly improved blood sugar levels in people with type 2 diabetes.” As for the drug’s safety, the release listed the most common side effects, which included among other things, “depressed mood (0.7% [placebo] vs. 5.8% [rimonabant 20 mg]).” The same day that the SERENADE results were announced, Sanofi-Aventis’ stock rose \$1.13 (2.6%) to \$45.09.

On December 8, 2006, Sanofi-Aventis announced that its October 26, 2006 resubmission was considered by the FDA to be a “complete, class 2 response,” meaning that the FDA would review it and act within six months. On February 12, 2007, Sanofi-Aventis issued a press release announcing its submission of the SERENADE study report to the FDA. On March 26, 2007, Sanofi-Aventis issued a press release announcing that the FDA EMDAC Meeting would be held on June 13, 2007. The release stated: “The Committee will discuss the efficacy and safety of rimonabant in obesity. Sanofi-Aventis is pleased to have the opportunity to present its data on rimonabant and to exchange with experts.”

On May 3, 2007, Sanofi-Aventis held its first quarter “Sales and Earnings Analyst/Investor Presentation.” The presentation highlighted the strong performance of Zimulti and portrayed the extremely large population of potential patients who could benefit by taking the drug. On May 10, 2007, Sanofi-Aventis submitted its “Briefing Information” for the FDA Committee’s meeting, including all of the updated data for all completed and ongoing clinical trials of Zimulti.

Defendants’ statements set forth above were materially false and misleading when made because defendants concealed data concerning Zimulti’s propensity to cause depression. On June 13, 2007, the committee met and made a unanimous decision (14-0) that Zimulti could not be recommended for approval. After the FDA’s decision on June 13, 2007, Sanofi-Aventis’ securities declined \$1.87, or 4.16%, closing at \$43.07 on heavy trading volume (8.9 million shares). The following day, the stock dropped to \$41.33 on even heavier trading volume (12.2 million shares).

III. ARGUMENT

A. The Global Funds Should Be Appointed Lead Plaintiff

The PSLRA establishes the procedure for the appointment of a lead plaintiff in “each private action arising under [the Exchange Act] that is brought as a plaintiff class action pursuant to the Federal Rules of Civil Procedure.” 15 U.S.C. §78u-4(a)(1); *see also* 15 U.S.C. §78u-4(a)(3)(B)(i). First, the plaintiff who files the initial action must publish a notice to the class within 20 days of filing the action, informing class members of their right to file a motion for appointment as lead plaintiff. 15 U.S.C. §78u-4(a)(3)(A)(i). Here, notice was published on *Business Wire* on November 13, 2007 in connection with the filing of the first-filed action. *See Rosenfeld Aff., Ex. C.* Within 60 days of publishing the notice, any person who is a member of the proposed class may apply to the court to be appointed as lead plaintiff, whether or not they have previously filed a complaint in the action. 15 U.S.C. §78u-4(a)(3)(A)(i)(II), (B)(i); *Rozenboom*, 2004 U.S. Dist. LEXIS 6382, at *7.

Second, the PSLRA provides that within 90 days after publication of the notice the court shall consider any motion made by a class member and shall appoint as lead plaintiff the member of the class that the court determines to be most capable of adequately representing the interests of class members. 15 U.S.C. §78u-4(a)(3)(B)(i). In determining the “most adequate plaintiff,” the PSLRA provides that:

[T]he court shall adopt a presumption that the most adequate plaintiff in any private action arising under this [Act] is the person or group of persons that –

(aa) has either filed the complaint or made a motion in response to a notice . . . ;

(bb) in the determination of the court, has the largest financial interest in the relief sought by the class; and

(cc) otherwise satisfies the requirements of Rule 23 of the Federal Rules of Civil Procedure.

15 U.S.C. §78u-4(a)(3)(B)(iii)(I).

The time period in which class members may move to be appointed lead plaintiff in this case, under 15 U.S.C. §78u-4(a)(3)(A)-(B), expires January 14, 2008. Pursuant to the provisions of the PSLRA and within the requisite time frame after publication of the required notice, the Global Funds have timely move this Court to be appointed lead plaintiff on behalf of the class.

1. The Global Funds Have the Largest Financial Interest in the Relief Sought by the Class

During the Class Period, the Global Funds purchased nearly 200,000 shares of Sanofi-Aventis securities and lost over \$1.9 million in connection therewith. To the best of their knowledge, there are no other applicants who have sought, or are seeking, appointment as lead plaintiff that have a larger financial interest. Therefore, the Global Funds satisfy the PSLRA’s prerequisite of having the largest financial interest. 15 U.S.C. §78u-4(a)(3)(B).

2. The Global Funds Otherwise Satisfy Rule 23 of the Federal Rules of Civil Procedure

In addition to possessing the largest financial interest in the outcome of the litigation, the lead plaintiff must also “otherwise satisf[y] the requirements of Rule 23 of the Federal Rules of Civil Procedure.” 15 U.S.C. §78u-4(a)(3)(B)(iii)(I)(cc). Of Rule 23(a)’s four prerequisites to class certification, only two – typicality and adequacy – directly address the personal characteristics of the class representative. Consequently, in deciding motions for appointment of lead plaintiff, the Court should limit its inquiry to the typicality and adequacy prongs of Rule 23(a), and defer examination of the remaining requirements until the lead plaintiff moves for class certification.

Under Rule 23(a)(3), the claims or defenses of the representative parties must be typical of those of the class. Typicality exists where the plaintiff’s claims arise from the same series of events and are based on the same legal theories as the claims of all the class members. *See Rossini v. Ogilvy & Mather, Inc.*, 798 F.2d 590, 598 (2d Cir. 1986). Typicality does not require that there be no factual differences between the class representatives and the class members because it is the generalized nature of the claims asserted which determines whether the class representatives are typical. The requirement that the proposed class representatives’ claims be typical of the claims of the class does not mean, however, that the claims must be identical. *See In re Crayfish Co. Sec. Litig.*, 2002 U.S. Dist. LEXIS 10134, at *14 (S.D.N.Y. 2002).

The Global Funds satisfy this requirement because, just like all other class members, they: (1) purchased Sanofi-Aventis securities during the Class Period; (2) purchased Sanofi-Aventis securities in reliance upon the alleged materially false and misleading statements issued by defendants; and (3) suffered damages thereby. Thus, the Global Funds’ claims are typical of those of other class members since their claims and the claims of other class members arise out of the same course of events.

Under Fed. R. Civ. P. 23(a)(4) the representative parties must also “fairly and adequately protect the interests of the class.” Fed. R. Civ. P. 23(a)(4) is met where: “(1) class counsel is ‘qualified, experienced, and generally able to conduct the litigation;’ and (2) class members do not have interests that are antagonistic to one another.” *Babcock v. Computer Assocs. Int’l*, 212 F.R.D. 126, 131 (E.D.N.Y. 2003) (citation omitted).

Here, the Global Funds are adequate to represent the class because their interests are aligned with the interests of the class because both suffered from artificial inflation of the price of Sanofi-Aventis securities and would benefit from the same relief. Furthermore, there is no evidence of antagonism between the Global Funds and the class. The Global Funds have also certified to their willingness to serve as representatives of the class. Rosenfeld Aff., Ex. B. In addition, as shown below, the Global Funds’ proposed lead counsel is highly qualified, experienced and able to conduct this complex litigation in a professional manner. Thus, the Global Funds satisfy the typicality and adequacy requirements of Fed. R. Civ. P. 23 for the purposes of this Motion.

B. The Court Should Approve the Global Funds’ Selection of Coughlin Stoia as Lead Counsel

The PSLRA vests authority in the lead plaintiff to select and retain lead counsel, subject to this Court’s approval. *See* 15 U.S.C. §78u-4(a)(3)(B)(v). Courts should not disturb the lead plaintiff’s choice of counsel unless it is necessary to “protect the interests of the class.” 15 U.S.C. §78u-4(a)(3)(B)(iii)(II)(aa). Because the Global Funds have selected and retained counsel experienced in litigating securities fraud class actions with the resources to prosecute this action to the greatest recovery possible for the class, its choice of lead counsel should be approved.

Coughlin Stoia is a 200-lawyer firm that is actively engaged in complex litigation, emphasizing securities, consumer and antitrust class actions. Coughlin Stoia possesses extensive experience litigating securities class actions and has successfully prosecuted numerous securities

fraud class actions on behalf of injured investors. Coughlin Stoia's securities department includes numerous trial attorneys and many former federal and state prosecutors, and utilizes an extensive group of in-house experts to aid in the prosecution of complex securities issues. *See* Rosenfeld Aff., Ex. D. Thus, the Court may be assured that in the event this Motion is granted, the members of the class will receive the highest caliber of legal representation available from Coughlin Stoia as lead counsel. *See Borochoff v. Glaxosmithkline PLC*, 246 F.R.D. 201, 2007 U.S. Dist. LEXIS 74621, at *11 (S.D.N.Y. 2007) ("Coughlin Stoia Geller Rudman & Robbins LLP . . . is well qualified and has successfully served as lead counsel . . . in numerous complex securities class actions.").

C. This Court Should Consolidate the Related Actions

The PSLRA provides that "[i]f more than one action on behalf of a class asserting substantially the same claim or claims arising under this chapter [is] filed," the court shall not appoint a lead plaintiff until "after the decision on the motion to consolidate is rendered." 15 U.S.C. §78u-4(a)(3)(B)(ii). To date, the Global Funds are aware of two related actions in this district against defendants:

CASE NAME	CASE NO.	DATE FILED
<i>City of Taylor General Employees Ret. Sys v. Sanofi-Aventis, et al.</i>	07-cv-10279	Nov. 13, 2007
<i>Smith v. Sanofi-Aventis, et al.</i>	08-cv-00021	Jan. 2, 2008

Under Rule 42(a) of the Federal Rules of Civil Procedure, consolidation is appropriate when the actions involve common questions of law or fact. Consolidation is particularly appropriate in securities class action litigations such as this. *See id.* All of the actions relate to the same series of false and misleading statements and arise under the Exchange Act. Therefore, consolidation is appropriate. *See Johnson v. Celotex Corp.*, 899 F.2d 1281, 1285 (2d Cir. 1990).

IV. CONCLUSION

For all the foregoing reasons, the City of Edinburgh Council on Behalf of the Lothian Pension Fund and New England Carpenters Guaranteed Annuity Fund respectfully requests that the Court: (1) appoint them as Lead Plaintiff; (2) approve their selection of Coughlin Stoia to serve as Lead Counsel; and (3) consolidate the related actions.

DATED: January 14, 2008

Respectfully submitted,

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[Proposed] Lead Counsel for Plaintiffs

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CERTIFICATE OF SERVICE

I hereby certify that on January 14, 2008, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on January 14, 2008.

s/ David A. Rosenfeld

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Electronic Mail Notice List

The following are those who are currently on the list to receive e-mail notices for this case.

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Manual Notice List

The following is the list of attorneys who are **not** on the list to receive e-mail notices for this case (who therefore require manual noticing). You may wish to use your mouse to select and copy this list into your word processing program in order to create notices or labels for these recipients.

- (No manual recipients)